

REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claims 1 and 13 have been amended to recite that each dose of tagging agent is in an aqueous suspension at a volume of at least about 20 ml and comprises about 10% to 80% w/v tagging agent. Support for this amendment can specifically be found in the originally filed written description at page 8 (lines 8-10) and at page 9 (line 11) through page 10 (line 2). Claim 7 has been amended to more clearly recite the foods being administered. Support for this amendment can specifically be found in the originally filed written description at page 13 (line 15) through page 16 (line 23). Claim 15 has been amended to change the phrase “the 20 to 36 hour administration period” to “a 20 to 36 hour administration period”. Claim 19 has been amended to incorporate the subject matter of claims 20 and 22, which have been canceled. Claims 3, 8, 9, 11, and 16 have likewise been canceled. Claims 1, 2, 4-7, 12-15, 17-19, 21, and 23-27 are pending.

Claim Objections

Claims 15 and 22 stand objected to because of certain informalities. Specifically, the Examiner argues the claims lack antecedent basis for certain terms. As noted above, claim 15 has been amended to change the phrase “the 20 to 36 hour administration period” to “a 20 to 36 hour administration period”. Claim 22 has been canceled. Accordingly, Applicant submits claim 15 contains no informalities and has proper antecedent basis, and Applicant requests reconsideration and withdrawal of the objection.

Rejections under 35 U.S.C. §102

Claims 19-21, 23, and 24 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Lauenstein et al., “MR Colonography with Barium-based Fecal Tagging: Initial Clinical Experience”, *Radiology*, 223(1):248-254 (hereinafter “Lauenstein et al., *Radiology* 223”). Applicant respectfully traverses this rejection.

Claims 19 has been amended to incorporate the subject matter of claim 22, which is not rejected under the presently cited section. Accordingly, Applicant respectfully submits the presently rejected claims 19, 21, 23, and 24 are not anticipated by Lauenstein et al., *Radiology* 223, and Applicant requests reconsideration and withdrawal of the rejection.

Rejections under 35 U.S.C. §102/103

Claims 1, 2, and 5 stand rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,331,116 to Kaufman et al. Applicant respectfully traverses this rejection.

Claim 1 presently recites a method comprising administering less than 7 doses of tagging agent over a 20 to 36 hour administration period, wherein each dose of tagging agent is a volume of at least about 20 mL and comprises about 10% to 80% w/v tagging agent. The Examiner has already noted the only disclosure provided by Kaufman et al. regarding tagging agent (i.e., column 16, lines 43-49), which discloses the use of a 2.1% w/v barium sulfate suspension. Thus, Kaufman et al. nowhere disclose or suggest the use of tagging agent at the significantly increased concentration of 10% to 80% w/v. Accordingly, Applicant submits claims 1, 2, and 5 are neither anticipated by nor obvious over Kaufman et al., and Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Rejections under 35 U.S.C. §103(a)

Claim 3 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kaufman et al. in view of U.S. Patent No. 6,477,401 to Johnson et al. and U.S. Patent No. 5,352,434 to Illig et al. Claim 3 has been canceled. Thus, Applicant respectfully requests withdrawal of this rejection.

Claim 4 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kaufman et al. in view of Illig et al. Applicant respectfully traverses this rejection.

The Examiner argues Illig et al. disclose that contrast agent volume should be kept low, and that 3 doses of 20 mL, as recited in claim 4, “can be considered low”. Applicant respectfully submits this is a vague interpretation of Illig et al. that does not properly distinguish between the terms “dosage” as used by Illig et al. and “volume” as presently claimed.

Present claim 4 recites the dosage in clear terms of both volume and concentration (i.e., 20 mL volume and 40% w/v concentration). Illig et al. likewise provide clear examples of what it considers to be a “low dose” in terms of both volume and concentration. In Examples 1-4 (column 8, line 64, through column 9, lines 21), Illig et al. teach formulations having a 10 mL total volume and having as concentration of 16.7% w/v, 16.8% w/v, or 19.4% w/v barium salt. Thus, the “low dose” taught by Illig et al. actually consists of one-half the volume recited in present claim 4 and less than one-half the tagging agent concentration. In light of these examples, a skilled person would not be motivated to administer three doses of tagging agent, each have a specific volume of 20 mL and a specific concentration of 40% w/v. At most, a skilled person would view Illig et al. as teaching that a “low dose” is some concentration at a volume of 10 mL. Accordingly, Applicant submits claim 4 is not obvious over the combination of Kaufman et al. and Illig et al., and Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claim 6 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Kaufman et al. in view of U.S. Patent No. 6,039,975 to Shah et al. Applicant respectfully traverses this rejection.

Present claim 1 (upon which claim 6 depends) recites that the tagging agent is in an aqueous suspension. Shah et al. is directed to a tablet. Moreover, as the Examiner notes, the Shah et al. tablet is designed to deliver its composition to the colon without premature delivery to the upper GI tract. An aqueous suspension would not achieve this end. Accordingly, Shah et al. teaches away from the presently recited aqueous suspension, and a skilled artisan would not be motivated to use the teachings of Shah et al. to prepare an aqueous suspension. Accordingly, Applicant requests reconsideration and withdrawal of the present rejection.

Claims 7-9, 11-12, and 25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,782,762 to Vining et al. in view of the Children’s Hospital at Westmead (CHW) Fact Sheet, and further in view of Shah et al. Applicant respectfully traverses this rejection.

The combined references do not disclose or suggest the combination of food items recited in present claim 7. Particularly, the combined references do not disclose or suggest the specific combination of the food items and a nutritional drink that provide the recited nutritional values,

specifically in combination with one or more doses of tagging agent. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 13-15 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., “MR Colonography Without Colonic Cleansing: A New Strategy to Improve Patient Acceptance”, (2001), *AJR* 177: 823-827 (hereinafter referred to as “Lauenstein et al. *AJR* 177”) in view of Callstrom et al., “CT Colonography without Cathartic Preparation: Feasibility Study”, (2001), *Radiology*, 219:693-698. Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al. *AJR* 177 and Callstrom et al. in view of Illig et al. Claim 17 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al. *AJR* 177, Callstrom et al., Kaufman et al., and Illig et al. Applicant respectfully traverses these rejections.

Claim 13 recites a method comprising administering a tagging agent that is an aqueous suspension at a volume of at least about 20 mL and comprising about 10% to 80% w/v tagging agent. Applicant submits the combination of Lauenstein et al. *AJR* 177 and Callstrom et al. does not disclose or suggest a method including the use of a tagging agent in this specific volume and concentration combination.

Claim 16 has been canceled.

Regarding claim 17, Applicant submits the Examiner has improperly combined the cited documents. Lauenstein et al. *AJR* 177 disclose the use of tagging agent at a volume of 200 mL (with no disclosed concentration). Callstrom et al. disclose the use of “dilute” barium sulfate (1.2%) at a volume of 225 mL. Kaufman et al. disclose the use of tagging agent at a volume of 250 mL. On the contrary, Illig et al. discloses the use of very low volumes. Specifically, Illig et al. teach formulations have 10 mL total volume and having 16.7% w/v, 16.8% w/v, or 19.4% w/v barium salt. Thus, a skilled person would recognize that Illig et al. is not combinable with Lauenstein et al. *AJR* 177, Callstrom et al., or Kaufman et al. since they teach volumes that are some 200 times greater than the Illig et al. formulations.

The Examiner has correctly pointed out, as well, that Illig et al stress that dosages should be kept as low as possible. Thus, a skilled person would not combine Illig et al. with Lauenstein et al. *AJR* 177, Callstrom et al., and Kaufman et al. to arrive at a composition that is both increased in volume and concentration. This simply goes against the teaching of Illig et al., and

the Examiner has pointed to nothing in any of the cited references that would motivate a skilled person to ignore the warning of Illig et al. and rather form a composition that is greatly increased in both volume and concentration.

In light of the above, Applicant respectfully submits that the subject matter of claims 13-15, 17, and 18 is not obvious over the various recited combinations of references. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejections.

Claim 22 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., *Radiology* 22. Claim 22 has been canceled.

Claim 26 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., *Radiology* 22 in view of Li et al., “An Image Segmentation Approach to Extract Colon Lumen Through Colonic Material Tagging and Hidden Markov Random Field Model for Virtual Colonoscopy”, 2002. Applicant respectfully traverses this rejection.

Applicant submits the Examiner has improperly combined the cited documents. Lauenstein et al., *Radiology* 22 expressly teaches that its method obviates bowel cleansing. Thus, a skilled person viewing Lauenstein et al., *Radiology* 22 would understand that the method therein has no need for a bowel cleansing regimen, even a mild laxative regimen, as taught by Li et al. The Examiner simply cannot argue that the cited documents would be combined to arrive at the invention when the documents teach away from one another. Lauenstein et al., *Radiology* 22 teach a method that does away with the need for laxative use, while Li et al. still teach the use of laxatives. Nothing in the documents has been pointed to as teaching that the laxatives of Li et al. should be combined with the laxative-free method of Lauenstein et al., *Radiology* 22. Accordingly, Applicant submits claim 26 is not obvious over the cited documents, and Applicant requests reconsideration and withdrawal of the present rejection.

Claim 27 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., *Radiology* 22 in view of Callstrom et al. Claim 27 has been canceled.

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT AND TRADEMARK OFFICE ON June 17, 2008.